Distribution Agreement

In presenting this thesis or dissertation as a partial fulfillment of the requirements for an advanced degree from Emory University, I hereby grant to Emory University and its agents the non-exclusive license to archive, make accessible, and display my thesis or dissertation in whole or in part in all forms of media, now or hereafter known, including display on the world wide web. I understand that I may select some access restrictions as part of the online submission of this thesis or dissertation. I retain all ownership rights to the copyright of the thesis or dissertation. I also retain the right to use in future works (such as articles or books) all or part of this thesis or dissertation.

Signature:

____________________________________ ____________________

Laura McPherson Date

Time on Dialysis Prior to Kidney Transplant Evaluation and Patient Uncertainty of Treatment Options

By

Laura McPherson
Master of Public Health

Epidemiology

Dr. Rachel Patzer
Committee Chair

Time on Dialysis Prior to Kidney Transplant Evaluation and Patient Uncertainty of Treatment Options

By

Laura McPherson

B.A., University of Wisconsin-Madison, 2013

Thesis Committee Chair: Rachel Patzer, PhD, MPH

An abstract of

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health

in Epidemiology

2016

Abstract

Time on Dialysis Prior to Kidney Transplant Evaluation and Patient Uncertainty of Treatment Options

By Laura McPherson

Objective: There are two primary treatment options for end stage renal disease (ESRD): dialysis and kidney transplant. Although kidney transplantation provides a significant survival benefit over long-term dialysis, many ESRD patients are uncertain, i.e., conflicted, about their decision to pursue kidney transplantation or remain on dialysis. ESRD patients' uncertainty about treatment of their kidney disease may be affected by cumulative time spent on dialysis prior to a kidney transplant evaluation. We aimed to investigate the association of time from dialysis start to kidney transplant evaluation with decisional conflict.

Methods: In a cross-sectional study using data from a clinical trial measuring effectiveness of a decision tool at three U.S. transplant centers, 464 patients were asked 10 questions, using a standardized question tool, assessing decisional conflict related to kidney transplant vs. dialysis. Scores could range from 0 to 100 (high) and patients were dichotomized as having (score >0) or not having (score=0) decisional conflict. Time on dialysis at evaluation start was abstracted from electronic medical records and categorized as never, <1 year, ≥1 year. Logistic regression was used to investigate associations of decisional conflict with time on dialysis prior to kidney transplant evaluation.

Results: Of 464 surveyed patients, 62% were male and 48% were African American; the average age was 51 years. Nearly half (49%) of patients had some decisional conflict about treatment options at the transplant evaluation. Those with decisional conflict were more likely to be male, African American, and publically insured, and less likely to be married, highly educated, and state a preference for transplant vs. dialysis at the time of evaluation compared to patients without decisional conflict. In the adjusted logistic analyses, time on dialysis was not statistically significantly associated with decisional conflict.

Conclusions: These results suggest that decisional conflict may be highly prevalent among ESRD patients being evaluated for transplant at a transplant center. Male, minority race, uninsured, uneducated, and patients with no social support are more likely to have decisional conflict. Identifying conflicted patients could inform intervention efforts to improve patients' abilities to make treatment decisions about their kidney disease before being evaluated by a transplant nephrologist.

Time on Dialysis Prior to Kidney Transplant Evaluation and Patient Uncertainty of Treatment Options

By

Laura McPherson

B.S., University of Wisconsin-Madison, 2013

Thesis Committee Chair: Rachel Patzer, PhD, MPH

A thesis submitted to the Faculty of the

Rollins School of Public Health of Emory University

in partial fulfillment of the requirements for the degree of

Master of Public Health

in Epidemiology

2016

Table of Contents

Chapter 1: Background

The Significance of Chronic and End Stage Renal Disease

Chronic kidney disease (CKD) is generally defined as “a condition in which your kidneys are damaged and cannot filter blood as well as healthy kidneys” (1). As of 2012, the overall prevalence of CKD in the United States was approximately 14% and it was estimated that more than 20 million people have been diagnosed with kidney disease to varying levels of severity (1, 2). CKD can lead to end stage renal disease (ESRD), also known as complete kidney failure, and is diagnosed in patients whose kidneys do not work well enough for them to survive (3). While the number of incident ESRD cases plateaued in 2010, there continues to be an increase in the number of prevalent cases by 21,000 cases per year (2). In 2013, there were approximately 660,000 ESRD prevalent cases in the United States, and close to 117,000 patients initiated treatment for ESRD by way of dialysis or kidney transplantation (2).

According to the Center for Disease Control’s 2013 National Vital Statistics Report, CKD is the 9th leading cause of death in the United States, with more than 47,000 CKD patients dying each year (4). Given the mortality and prevalence rates of kidney disease, it is apparent that this condition is a significant public health issue and economic burden in the United States. As part of the nation’s effort to promote health and prevent disease, the U.S. Department of Health and Human Resources launched the Healthy People initiative in 2010, with one of the main priorities being to “reduce new cases of CKD and its complications, disability, death, and economic costs” (2). Despite this initiative, data collected by the national surveillance system for CKD, known as the United States Renal Data System (USRDS), found that CKD continues to be a major source of lost productivity, physician encounters, and hospitalizations for patients (2). In 2013 Medicare spent over $89 billion of its total expenditures on patients being treated for all levels of kidney disease and approximately $29 billion to treat patients who have gone into kidney failure (4).

Chronic and End Stage Renal Disease Clinical Risk Factors

Both domestically and internationally, researchers have investigated the risk factors most strongly associated with the development of CKD and the progression to ESRD. Identifying characteristics of individuals at the highest risk for CKD will help predict the potential burden of CKD and inform future intervention efforts to reduce the incidence and prevalence of the disease. In the majority of developing and in all developed countries, diabetes mellitus, hypertension, and obesity are increasingly common non-communicable diseases and previously identified risk factors for CKD (5). However, in the United States, the most frequent conditions associated with CKD include diabetes (45%), hypertension (28%), and chronic glomerulonephritis (5%) (5). Individuals with the aforementioned diseases are at a much higher risk of developing CKD than individuals without these ailments. As of 2014, about 1 in 3 adults with diabetes and 1 in 5 adults with hypertension has also been diagnosed with CKD in the United States (1).

Disparities in Chronic and End Stage Renal Disease

In addition to the contribution of comorbid conditions on the development of CKD, there are several well-documented inequalities among various genetic, racial/ethnic, and individual socioeconomic characteristics and their associations with increased incidence and prevalence of CKD (6). Previous literature found that individuals with an immediate family member who has initiated dialysis or received a kidney transplant are at higher risk for progressive kidney disease. In a cross-sectional study conducted by researchers at Wake Forest University School of Medicine, approximately 23% of incident dialysis patients reported having an immediate relative with ESRD and results of the study found family history of ESRD to be directly associated with diagnosis of ESRD at a younger age and primary cause of ESRD (7). Similarly, in a study based upon the renal REGARDS (Reasons for Geographic and Racial Differences in Stroke) cohort, individuals with a family history positive for ESRD were 2.6 times more likely to progress to ESRD than individuals without a family history (8). Additionally, family history of ESRD was found to be positively associated with the African American population within the study, with race and ethnicity being another well-established predictor of CKD found within the literature (8).

Minority populations are at an elevated risk of progressing from CKD to kidney failure. However, it should be noted that among these populations there are also high rates of clinical diagnoses harmful to the kidneys, including diabetes and hypertension (2). The prevalence of CKD among Medicare patients aged 65+ is approximately 50% higher among African Americans compared to Whites (2). Additionally, American Indians are 1.8 times more likely to be diagnosed with kidney failure than Whites, while the Hispanic ESRD population has increased by greater than 70% in the last 15 years (2).

While racial and ethnic disparities are known to be associated with low socioeconomic status in the United States, individual-level socioeconomic characteristics are also found to be independently associated with increased incidence of CKD and progression to ESRD (6). As observed in previous literature, there is an independent association found between higher educational status and low income and the diagnosis of various chronic diseases, one of which is reduced kidney function (9). Similarly, these findings suggest that increased prevalence of CKD among patients with lower socioeconomic status may also be attributable to low health literacy and a patient's ability to comprehend discussions with their medical providers about their kidney disease (10).

End Stage Renal Disease Treatment Options

There are two main treatment options for patients diagnosed with ESRD, dialysis and kidney transplantation. Compared to dialysis, kidney transplantation is considered to be the gold standard treatment for most patients with ESRD secondary to improved quality of life, decreased hospitalization rates, cost-effectiveness, and better survival outcomes (11, 12). Likewise, based upon 110 cohort studies in a systematic review analyses, 76% of studies found an association between kidney transplantation and lower risk of mortality among ESRD patients (12). Despite these well-known findings, as of 2013, 63.7% and 6.8% of ESRD prevalent cases in the US were treated by means of hemodialysis and peritoneal dialysis, respectively, while only 29.2% of patients underwent a kidney transplant (2).

Disparities in Access to Kidney Transplantation

As previously mentioned, kidney transplantation is associated with improved quality of life, lower cost, and decreased mortality in comparison to hemodialysis or peritoneal dialysis treatment (13). Given the increased recognition of kidney transplant advantages, the number of patients interested in transplantation has also increased (14). In contrary to these findings there continues to be health disparities, or more specifically "potentially avoidable differences in health between groups of people who are more or less advantaged socially" in access to kidney transplantation (15). Differences in transplantation rates and outcomes among vulnerable populations has been well-documented within the literature, specifically emphasizing sociocultural (race, sex, educational), socioeconomic (income, insurance status, employment), and geographic disparities (16, 17).

According to the USRDS, the prevalence of ESRD among African Americans is 3.7 times that of the white population in the United States (2). Despite the increased prevalence, African Americans only receive approximately one-fourth of deceased donor kidneys and comprise about one-third of the population on dialysis (13). As first investigated by Dr. Caleb Alexander and his team affiliated with the University of Pennsylvania Department of Medicine, there are substantial decreases in the rate at which African Americans express interest in transplantation, follow through with a pre-transplantation evaluation, and undergo a kidney transplantation as compared to whites (16). More recently, researchers at Emory University found significant racial differences in the proportion of African American ESRD patients who begin the kidney transplant evaluation process compared to white ESRD patients within a cohort of ESRD patients who had been referred for a kidney transplant evaluation at the Emory Transplant Center. (18). Various socioeconomic measures, including educational attainment, employment, income, insurance status, and neighborhood poverty were found to be associated with the completion of several steps in the kidney transplantation process, and there was an overall trend of higher socioeconomic status with each successive step in the process (18). Given these findings, further exploration into patient characteristics closely associated with completion of earlier steps of the kidney transplantation process will be of interest to researchers focusing on disparities in kidney transplant.

As reported by the Institute of Medicine, health literacy is defined as “the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions” (19). Health literacy contributes to ESRD patients’ knowledge of their kidney disease, patient-provider interactions, and ability to make decisions about which treatment options are optimal for their condition (20). While the literature involving health literacy within a kidney transplant specific population is minimal, three studies found an association between low health literacy and likelihood of referral for transplantation (20). More recently, a cross-sectional study conducted at the Medical University of South Carolina in 2014 found a higher likelihood of kidney transplantation among patients who scored higher on three validated tools used to measure health literacy, further supporting previous hypotheses predicting low health literacy as a barrier to initiating the kidney transplantation process (21). A more recent study conducted by researchers at John Hopkins University School of Medicine found that in addition to the health literacy barrier, patient education is a vital component to patients’ pursuit of a transplant (22). Among just under 250,000 incident ESRD cases, based upon USRDS 2005-2007 data, almost one-third of patients had not been informed of kidney transplantation at the time of Centers for Medicare & Medicaid Services mandatory filing of the 2728 Medical Evidence form upon initiation of dialysis (22). Disparities in the dissemination of kidney transplant information reflect disparities in access to kidney transplant among previously discussed disadvantaged groups and is another barrier reducing access to kidney transplant.

Beyond the influence of individual sociocultural and socioeconomic factors to disparities in access to kidney transplantation, researchers have identified an association between where ESRD patients live and access to transplant (13, 14, 23). Previous investigators found significant differences in access to the kidney transplant waitlist by state, with the lowest rates of kidney transplantation in the Southeastern region of the United States (17, 23). Upon further investigation of this association, researchers found that regional disparities are likely a reflection of sociocultural disparities by race and the variation of racial disparities in income and education across regions (13). As exemplified by the myriad of characteristics contributing to ESRD patients' access, disparities in kidney transplant access are observably multifactorial in nature. Investigators continue to research the relationship among these factors and their association with access to the kidney transplant waitlist. Further understanding of the means to overcome these well-known sociocultural and socioeconomic disparities is critical to improving access to optimal healthcare among the United States ESRD population.

The iChoose Kidney Clinical Trial

The iChoose Kidney research study was a randomized clinical trial conducted at three large transplant centers in the United States, including Emory Transplant Center in Atlanta, GA, Columbia University Medical Center in New York City, NY, and Northwestern University Transplant Center in Chicago, IL from November 2014 to October 2015. The randomized study was designed to evaluate a shared clinical decision aid, iChoose Kidney, which is accessible via iPad, iPhone, or the web (24). The tool is intended to be used by ESRD patients and their providers in the clinic to initiate and guide discussion regarding decision-making about treatment options for their kidney disease, i.e., long-term dialysis or kidney transplantation. More specifically, the application provides ESRD patients with an individualized comparison of mortality and survival risk estimates of remaining or initiating long-term dialysis versus deceased or living donor kidney transplantation (25).

As part of the trial's protocol, ESRD patients were consented and recruited for study participation at the time of their kidney transplant evaluation appointment with a transplant nephrologist. Study participants were randomized to proceed with their appointment either without (26) or with (intervention) the use of iChoose Kidney application during their discussion with their provider. All participants completed a survey both before and after their evaluation appointment, with one portion of the questionnaire assessing decisional conflict in relation to the treatment of their kidney disease.

The Decisional Conflict Scale

Decisional conflict can be defined as "personal uncertainty about which course of action to take when choice among competing options involves risk, regret, or challenge to personal life values" (27). There are often multiple ways to appropriately treat or manage a chronic disease, and on occasion, it may be up to the patient to pursue one treatment option versus an alternative(s). A validated measurement tool, created by AM O'Connor in 1993, can be used to assess decisional conflict, i.e., patient uncertainty regarding treatment options (28). The tool, known as the decisional conflict scale (DCS), not only measures uncertainty in choosing options, but also measures several modifiable factors contributing to uncertainty, such as feeling uninformed or unsupported, as well as "perceived effectiveness of the decision" (29). As described in AM O'Connor's user manual, there are four versions of the scale: 16-item statement format, 16-item question format, 10-item low literacy question format, and 4-item clinical practice format (28).

The DCS was validated in previous studies. For instance, a cross-sectional study of cancer patients' decision whether to endure palliative chemotherapy found that the DCS can be validly used to measure the "quality of medical decision making" (29). Additionally, a randomized control trial found the DCS to be a reliable measure for assessing the conflict felt by caregivers' making end-of-life decisions for terminally ill patients (30). Moreover, using a modified version of O'Connor's DCS in a cross-sectional study, researchers found that the scale could be used to validly quantify vulnerable patients' uncertainty regarding decisions about different treatment options for chronic neurologic or cardiac conditions (31). To the best of our knowledge the DCS has not been used to investigate patient uncertainty regarding kidney disease treatment options within the ESRD population.

Importance of Evaluating ESRD Patients' Treatment Option Uncertainty

ESRD patients are likely to be presented with kidney disease treatment options that promote decisional conflict. Despite exploration by many researchers and evidence supporting kidney transplantation as the preferred treatment method for majority of United States ESRD patients, disparities in access to kidney transplant continue to be prevalent across the country (12, 16). In a systematic study assessing the current clinical benefits of kidney transplant compared with dialysis, approximately 75% of 77 studies found an association between lower mortality and kidney transplantation (12). More specifically, previous research supports the association of longer wait times on dialysis prior to kidney transplantation with lower chance of long-term survival (32). One of the strongest predictors of long-term transplant outcomes is argued to the time from when patients are diagnosed with ESRD until they receive a kidney transplant (33).

Given the above predictor for long term-outcomes, it is critical for ESRD patients to not only receive a referral for an evaluation with a transplant nephrologist, but to also express interest in undergoing transplant and actually begin the transplant evaluation process. In 2012, researchers from Emory University found that among 2,291 ESRD patients referred for kidney transplant to the Emory Transplant Center, approximately 50% of patients did not show up to their first evaluation appointment (18). The prevalence of decisional conflict among the United States ESRD population is unknown, and unresolved decisional conflict could be one of the potential reasons that ESRD patients are hesitant to follow through with their first transplant evaluation appointment. Despite being identified as good candidates for kidney transplant by referring physicians, ESRD patients, both on and off dialysis, may remain uncertain about their treatment options. After being referred for transplant, conflicted ESRD patients may be more likely to frequently change their mind about undergoing a kidney transplant, which in turn delays decision-making and increases the time between their ESRD diagnosis and transplant procedure (34). Using a validated measurement scale to assess ESRD patients' decisional conflict shortly after being referred for transplant may help medical providers identify factors contributing to patients' uncertainty about treatment.

The process by which an ESRD patient is referred for kidney transplant evaluation and the transplant process itself are extremely complex, thus making it vital that all treatment options are presented comprehensively and clearly to patients by medical providers (20). ESRD patients' capacity to decide between initiating or maintaining long-term dialysis versus undergoing a kidney transplant could be influenced by a multitude of factors, some of which include access to knowledge about ESRD, understanding ESRD treatment modalities and its effect on quality of life, ability to communicate appropriately with medical providers, support from family and friends, motivation and coping mechanisms, and prognostic uncertainty (35). Previous analyses found a higher prevalence of anxiety and depression among dialysis versus post-kidney transplant patients (36), and these feelings could also be associated with decisional conflict. By evaluating ESRD patients' level of decisional conflict, there is potential to reduce patients' time from ESRD diagnosis to kidney transplantation, and ultimately improve post-transplant survival outcomes. Moreover, identifying ESRD patients who feel particularly uncertain or conflicted could help inform future intervention efforts at dialysis facilities and transplant centers.

Chapter II: Manuscript

Time on Dialysis Prior to Kidney Transplant Evaluation and Patient Uncertainty of Treatment Options

By Laura McPherson

Abstract

Objective: There are two primary treatment options for end stage renal disease (ESRD): dialysis and kidney transplant. Although kidney transplantation provides a significant survival benefit over long-term dialysis, many ESRD patients are uncertain, i.e., conflicted, about their decision to pursue kidney transplantation or remain on dialysis. ESRD patients' uncertainty about treatment of their kidney disease may be affected by cumulative time spent on dialysis prior to a kidney transplant evaluation. We aimed to investigate the association of time from dialysis start to kidney transplant evaluation with decisional conflict.

Methods: In a cross-sectional study using data from a clinical trial measuring effectiveness of a decision tool at three U.S. transplant centers, 464 patients were asked 10 questions, using a standardized question tool, assessing decisional conflict related to kidney transplant vs. dialysis. Scores could range from 0 to 100 (high) and patients were dichotomized as having (score >0) or not having (score=0) decisional conflict. Time on dialysis at evaluation start was abstracted from electronic medical records and categorized as never, <1 year, ≥1 year. Logistic regression was used to investigate associations of decisional conflict with time on dialysis prior to kidney transplant evaluation.

Results: Of 464 surveyed patients, 62% were male and 48% were African American; the average age was 51 years. Nearly half (49%) of patients had some decisional conflict about treatment options at the transplant evaluation. Those with decisional conflict were more likely to be male, African American, and publically insured, and less likely to be married, highly educated, and state a preference for transplant vs. dialysis at the time of evaluation compared to patients without decisional conflict. In the adjusted logistic analyses, time on dialysis was not statistically significantly associated with decisional conflict.

Conclusions: These results suggest that decisional conflict may be highly prevalent among ESRD patients being evaluated for transplant at a transplant center. Male, minority race, uninsured, uneducated, and patients with no social support are more likely to have decisional conflict. Identifying conflicted patients could inform intervention efforts to improve patients' abilities to make treatment decisions about their kidney disease before being evaluated by a transplant nephrologist.

Introduction

Chronic kidney disease (CKD) is defined as any condition that damages the kidneys and causes decreased kidney function over time (2). In 2014, it was estimated that CKD was diagnosed in more than 20 million United States adults, and that in nearly 650,000 adults, the disease progressed to end stage renal disease (ESRD), or complete kidney failure (1).

Compared to long-term dialysis, kidney transplantation is the preferred method of treatment for most ESRD patients, offering a better quality of life, decreased likelihood of hospitalization, lower treatment cost, and increased survival (11, 12). Historically, minority and lower socioeconomic populations as well as patients uneducated about kidney transplant suffer from disproportionate access to kidney transplantation (16). For example, in previous studies it was found that African Americans and Native Americans were approximately 3.3 times more likely to progress to ESRD than were non-Hispanic whites. However, only 25% of kidney transplant recipients in 2014 were African American patients (37). Multiple socioeconomic factors, including educational attainment, employment status, income level, insurance status, and neighborhood poverty, were found to have an effect on completion of multiple steps in the kidney transplantation process, with a notable trend being higher socioeconomic status with completion of each successive step in the process (18).

Several barriers have been identified as contributing to disparities in transplantation and include, but are not limited to, biologic factors, geographic location, racism, and socioeconomic status (38). In addition, earlier research found that kidney transplantation education at dialysis facilities plays a crucial role in patients' likelihood of receiving a transplant and their ability to make an informed decision regarding their treatment options (22). A previous multicenter cross-sectional study found that approximately 30% of 327 study participants, had a low perceived knowledge of treatment options, which could hinder their capacity to decide whether or not to pursue transplantation or remain on dialysis long-term (39, 40). Furthermore, among a cohort of 250,000 incident ESRD cases, only two-thirds of patients indicated they had been informed about transplant as a treatment modality at the time of Centers for Medicare & Medicaid Services mandatory filing of the 2728 Medical Evidence form, reducing their likelihood of receiving a transplant (22).

Patients’ uncertainty concerning treatment options can be assessed through a validated measurement tool, the decisional conflict scale (DCS), developed by AM O’Connor in 1993 (28). As patients progress further into the decision-making process, the DCS evaluates treatment option uncertainty, contributing factors to uncertainty, and “perceived effectiveness of the decision” (29). The DCS was validated in previous studies. For instance, a cross-sectional study of cancer patients’ deciding whether to endure palliative chemotherapy found that the DCS can be validly used to measure the “quality of medical decision making” (29). Additionally, a randomized control trial found the DCS to be a reliable measure for assessing the conflict felt by caregivers’ making end-of-life decisions for terminally ill patients (30). Finally, using a modified version of O’Connor’s DCS in a cross-sectional study, researchers found that the scale could be used to validly quantify a vulnerable patients’ uncertainty regarding decisions about different treatment options for chronic neurologic or cardiac conditions (31).

To the best of our knowledge, the prevalence of decisional conflict is unknown among the ESRD population and the DCS has not been used to investigate ESRD patient uncertainty regarding kidney disease treatment options. ESRD patients’ uncertainty about undergoing kidney transplantation, i.e., decisional conflict, may be affected by cumulative time spent on dialysis prior to kidney transplant evaluation. For instance, patients on longer-term dialysis may feel more conflicted because they are less knowledgeable about which treatment is the most beneficial for them or they do not feel supported in their decision to pursue transplantation. Using a cross-sectional design, we investigated the association of time from dialysis initiation to kidney transplant evaluation with decisional conflict at three unique transplant centers. We hypothesized that ESRD patients who are evaluated for kidney transplant within one year of dialysis initiation or are evaluated for transplant prior to dialysis initiation may have less decisional conflict compared to ESRD patients who are evaluated for transplant more than one year after beginning dialysis.

Methods

This study was a cross-sectional analysis of baseline data collected on participants in a randomized controlled trial, iChoose Kidney. The Emory Institutional Review Board approved this study (IRB1485996) and written informed consent was obtained for all study participants.

Data Collection Procedures – iChoose Kidney Clinical Trial

The iChoose Kidney Decision Aid for Treatment Options randomized trial was conducted at three large transplant centers in the United States, including the Emory Transplant Center in Atlanta, GA, the Columbia University Medical Center in New York, NY, and the Northwestern University Transplant Center in Chicago, IL from November 2014 to October 2015. The randomized study was designed to evaluate a shared decision-making support tool, iChoose Kidney, which is accessible via iPad, iPhone, or the web. The tool is intended to be used by ESRD patients and their providers in the clinic to initiate and guide discussion regarding decision-making about treatment options for their kidney disease, i.e., dialysis or kidney transplantation and the differences in survival outcomes between treatment methods. The study is registered at clinicaltrials.gov (NCT02235571).

Study Protocol and Population

A total of 472 incident ESRD patients participated in the study between November 2014 and October 2015 by a study coordinator at each of the three sites during their kidney transplant medical evaluation. To meet study inclusion criteria, patients must have been between the age of 18 and 70 years, English-speaking, with no severe cognitive or visual impairments. Patients with a history of solid organ or multiorgan transplants were not eligible for the study. Patients were consented and asked to complete a baseline survey, which included a 10-item portion assessing decisional conflict. The survey was designed with a web-based tool, SurveyMonkey, and administered via an iPad or paper, depending on the participant's preference. A detailed protocol of the randomized study procedures was submitted for publication and is currently under review (41).

Using selected demographic and socioeconomic questions and the DCS portion of the baseline survey, a cross-sectional study was performed. Of the 472 patients initially recruited, participants were excluded from analyses if more than one of the 10 DCS questions were missing a response (n=8). A total of 464 participants were deemed eligible for analyses.

Study Variables

Our exposure variable was time from the date of dialysis initiation to the date of medical evaluation for a kidney transplant by a transplant nephrologist. This measure was abstracted from patients' electronic medical records (EMR), and converted into number of days to maintain unit standardization among study participants. Based on the distribution of the variable, time on dialysis was categorized as preemptive referrals (no dialysis prior to evaluation), on dialysis less than one year prior to evaluation, and greater than or equal to one year on dialysis prior to evaluation.

The outcome variable in these analyses was ESRD patient uncertainty about kidney disease treatment options (dialysis versus kidney transplant), adapted from version 4.3 of the validated DCS, which is written in a 10-item, 3-response category format (28). This particular version of the DCS was selected for the study given its recommendation to be used on individuals with "limited reading or response skills" (28). Participants were first asked a question asking preference of treatment options (dialysis versus kidney transplantation), which was not part of the DCS. This question was followed by the 10 DCS questions regarding uncertainty about the option they preferred in the previous question. Items were given a score value of 0, 2, or 4 for responses "Yes", "No" or "Unsure," respectively. Per O'Connor's DCS User manual, the 10 items were summed, divided by 10, and multiplied by 25 to determine the total DCS score. A total of n=11 patients were missing one item from the scale; the total score for participants with missing data was calculated by summing the 9 non-missing items, dividing by 9, and multiplying by 25. Scores could range from 0 (no decisional conflict) to 100 (extremely high decisional conflict). The validated and reliable measurement tool predicts that patients with high decisional conflict will be more likely to prolong making a choice and be less knowledgeable about their decisions (28). Since approximately half of the patients within our study population had no decisional conflict, we dichotomized the DCS variable into a score of 0 (no decisional conflict) and a score greater than 0 (any decisional conflict).

Selected patient characteristics were utilized to further describe the ESRD population. In addition to the data collected in the baseline survey during the ESRD patients' kidney transplantation medical evaluation, demographic and clinical characteristics were abstracted from patients' electronic medical records (EMR), also at the time of their evaluation appointments. Demographic characteristics included age (in years), sex, and race/ethnicity (categorized as African American, White non-Hispanic, White Hispanic, and Other). Given the inconsistencies in the EMR categorization of race and ethnicity among the three transplant centers, self-reported race collected in the baseline survey was used in analyses. In the event of missing self-reported race data, the EMR data was used. Both age and sex were abstracted directly from the EMR and included in analyses.

Clinical characteristics included selected comorbidities, BMI > 35 kg/m^2, hypertension, diabetes, cardiovascular disease, albumin level < 3.5 g/dL, and type of dialysis (not on dialysis, hemodialysis, or peritoneal dialysis). Given previous research involving the ESRD population and access to transplantation, select socioeconomic characteristics were also collected in the baseline survey, including marital status (married, non-married), educational attainment (high school diploma or less, some college/vocational school or more), employment status (unemployed, employed, retired), primary health insurance status (private, non-private), and household income before taxes. Additional variables of social support (defined as the patient having at least one family member or friend accompanying them to their evaluation appointment), treatment preference (transplant vs. dialysis vs. unsure), patient health literacy score (calculated using Newest Vital Sign on a scale from 0 – 6), and patient numeracy score (calculated using the Lipkus scale on a scale from 0 to 11) were also collected at time of recruitment (42, 43). Aside from health literacy and numeracy scores, which were collected in the follow-up survey, all additional variables were collected in the baseline survey of the iChoose Kidney Clinical Trial. Further details of this clinical trial can be found in the iChoose Kidney Clinical Trial protocol currently under review for publication (41). Transplant center location was used to represent participants' geographic location. However, institutions were identified as Transplant Center A, B, and C to ensure patient confidentiality.

Data Cleaning and Quality Control Assessment Activities

Data cleaning and analyses were conducted using SurveyMonkey, MS Excel, and SAS version 9.4 (Cary, NC). Data from the iChoose Kidney Clinical Trial were merged with data from the electronic medical record (EMR) by EMR number. During the recruitment phase of the iChoose Kidney randomized study, study coordinators created an Excel spreadsheet to ensure that study inclusion criteria were upheld and missing data were documented. Study site coordinators communicated via a monthly conference call to ensure that patient recruitment and data collection methods were standardized among the three transplant centers.

Analyses

Descriptive statistics to compare study participants across the three categories of time from dialysis initiation to a medical evaluation appointment for kidney transplantation (preemptive referral, dialysis <1 year, dialysis ≥ 1 year) were calculated and compared using either t-tests or one-way ANOVA tests for continuous variables and chi-square tests for categorical variables. For all analyses, results were considered to be statistically significant at alpha <0.05. We used crude and adjusted logistic models to evaluate the association between the presence of any (vs. no) decisional conflict and time from dialysis start to the medical evaluation appointment at a transplant center for kidney transplantation. Interaction and confounding were assessed by first examining each of the selected patient characteristics individually in a model with only the outcome variable. No significant interaction terms were found in the analyses. Confounding was then assessed using a backwards elimination approach by starting with all candidate variables in the model and testing the removal of each variable. Variables were removed from the model if the odds ratio after deletion did not deviate more than 10% from the model with all candidate variables (44). Of note, to determine the best suitable model for our analyses, both estimate (odds ratios) and precision (95% confidence intervals) were taken into consideration (44). Our final adjusted model included age, sex, race, serum albumin, dialysis type, marital status, educational attainment, insurance status, health literacy, and geographic location as potential confounders for the association between time on dialysis and decisional conflict.

Results

Patient Characteristics

Baseline characteristics by primary exposure, time from dialysis initiation to medical evaluation for kidney transplantation by a transplant nephrologist, are shown in Table 1. The chi-square test of independence for categorical variables and the one-way ANOVA for age, literacy score, and numeracy score were used to assess differences in demographic, clinical, and socioeconomic characteristics between the three groups of patients (preemptive referrals, dialysis <1 year, and dialysis ≥1 year); statistically significant differences were found for sex, race, marital status, education level, employment status, household income before taxes, health literacy, and numeracy (Table 1).

Of the 464 patients included in the preliminary analyses, 152 (32.8%) were preemptively referred for kidney transplant evaluation, 156 (33.6%) had been on dialysis <1 year, and 156 (33.6%) had been on dialysis for ≥1 year (Table 1). A total of 62.1% of all patients were male and the mean age was 50.6 years (s.d. = 10.2). Approximately 48% of the patients were African American, 35% non-Hispanic White, 11% Hispanic, and 7% other race (including Asian, Multiracial, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, Middle Eastern, and East Indian). At the time of medical evaluation, 78.7% of all patients had been previously diagnosed with hypertension, while 18% had a BMI >35 kg/m^2. A total of 80% had Medicare or Medicaid as their primary insurance and 32% had earned a high school diploma. The mean health literacy score and numeracy score for all patients was 3.6 out of 6 (s.d. 2.1) and 6.1 out of 11 (3.2), respectively.

The primary outcome variable, decisional conflict score, was dichotomized as no decisional conflict (score = 0) and any decisional conflict (score >0), with 52% of patients having a decisional conflict score of 0 (Table 2). Among patients with decisional conflict (n=239), approximately 68% were male and 54% were African American. Comorbidities, including BMI >35 kg/m^2, hypertension, diabetes, cardiovascular disease, and low serum albumin, were more prevalent among conflicted patients, while non-conflicted patients were more likely to be married, more highly educated, employed with a greater annual income, privately insured, and receive a higher score on both the literacy and numeracy tests. The median number of days on dialysis prior to evaluation for patients without decisional conflict was 293 days, which is approximately 48 days lower than the median for patients with decisional conflict.

Association Between Patient Time on Dialysis and Decisional Conflict Score

In bivariate analyses of patient characteristics, sex, race/ethnicity, institution, diabetes, albumin level, marital status, education level (categorized as high school diploma or less vs. some college/vocational school or more), employment status, primary health insurance status (categorized as private vs. non-private), health literacy, and numeracy were all statistically or borderline statistically significantly associated with decisional conflict. Given these findings, crude and logistic models adjusting for potential confounders were performed to investigate our primary hypothesis (Table 3).

In the crude logistic model, dialysis initiation <1 year prior to kidney transplant evaluation was not associated with having decisional conflict [OR: 0.95; 95% CI: (0.61, 1.50)], while dialysis ≥1 year prior to kidney transplant evaluation was positively associated with having decisional conflict between treatment options [OR: 1.52; 95% CI: (0.97, 2.38)] compared to patients not on dialysis prior to evaluation (Table 3). In the multivariable logistic regression model adjusted for demographic and clinical characteristics, there was a null effect between ESRD patients on dialysis <1 year and having decisional conflict (OR: 0.96; 95% CI: 0.51, 1.79), while ESRD patients on dialysis ≥ 1 year were 1.40 times as likely to have decisional conflict (95% CI: 0.71, 2.75) (Table 3). In our final model, adjusted for demographic, clinical, socioeconomic, and geographic characteristics, the effect estimate for ESRD patients on dialysis <1 year remained the same as the previous model (adjusting for demographic and clinical factors only) at 0.96 (95% CI: 0.48, 1.93). However, the effect estimate for ESRD patients on dialysis ≥ 1 year decreased (from the previous model) to 1.28 (95% CI: 0.60, 2.70) (Table 3). The following covariates had some missing data: race (n=1), albumin <3.5 g/dL (n=17), marital status (n=5), educational status (n=6), and literacy (n=22); we conducted a complete-case analyses, and thus final multivariable modeling results were conducted among n=390 patients.

Treatment Preferences by Decisional Conflict Score

Regardless of decisional conflict score, when asked which treatment method they most preferred, a majority of participants selected kidney transplant versus initiating or remaining on dialysis (Figure 1). Among patients with some decisional conflict, 70% preferred kidney transplant, while 80% of non-conflicted patients favored kidney transplant over dialysis treatment (Figure 1). Among participants with any decisional conflict, 7% indicated they were unsure about which treatment option they preferred, while no non-conflicted patients replied as unsure about their preference (Figure 1).

Discussion

Approximately half of our study population had some degree of uncertainty regarding ESRD treatment options at the time of evaluation by a transplant nephrologist. While patients may begin to feel conflicted about their treatment options shortly after being diagnosed with ESRD, this finding suggests that those feelings of uncertainty do not always resolve by the time patients are evaluated for a kidney transplant. When comparing conflicted vs. non-conflicted patients, demographic and socioeconomic characteristics differed between the two groups. Patients with decisional conflict were more likely to be male, African American or Hispanic, and less likely to be married, college educated, employed, privately insured, or as highly literate as patients certain about their treatment decision. Despite patients' level of uncertainty, a majority of patients indicated they preferred transplant to long-term dialysis. However, several patients still reported feeling unsure about either option at the time of their transplant evaluation.

Additionally, patients with decisional conflict spent, on average, a longer time on dialysis prior to be evaluated for a kidney transplant. Patients on dialysis for more than one year appeared to be unhealthier and of lower socioeconomic status than patients who have never been on dialysis. Patients on dialysis for a longer period of time were also more likely to have been diagnosed with diabetes, as well as unemployed, insured by Medicare or Medicaid, with income below the poverty line, and not perform as well on the health literacy and numeracy tests compared to patients referred for transplant evaluation prior to initiating dialysis.

Given these results, it is critical that medical providers and dialysis facility staff introduce transplantation as a potential treatment modality to patients, even prior to diagnosis of ESRD. For example, nephrologists could provide transplant education materials, such as pamphlets or videos, to CKD patients who are at risk of progressing to ESRD at their routine appointments. Providing education materials to patients at earlier stages of CKD would give patients more time to consider their options, formulate questions for medical staff, and surround themselves with a supportive group of family and friends. As indicated by our results, decisional conflict may be more prevalent among patients with less education, lower literacy and little support from family and friends. Therefore, in addition to the dissemination of transplant education materials, patients would also benefit from in depth one-on-one discussions with medical providers concerning transplant, as well as the opportunity to converse with previous kidney transplant recipients about the process. The socioeconomic characteristic of the conflicted patients in our study population reinforce previously published results regarding the importance of communication between physicians and patients managing chronic diseases. Among approximately 240,000 incident ESRD cases in a 2012 cohort study, only 69.9% of patients recalled being informed of transplant as a treatment option upon initiating dialysis (22). Moreover, among 2,291 ESRD patients referred for transplant, only 55% actually went to their first evaluation appointment with a transplant nephrologist (18). Overall, characteristics of conflicted patients in our study population build upon results from previous literature in that a portion of ESRD patients' uncertainty may be attributed to a lack of communication about transplant with their medical providers or a need for more transplant educational materials and resources appropriate for their literacy level. Additionally, conflicted patients could benefit from conversing with post-transplant recipients who speak about their positive experiences with transplant.

In addition to evaluating the characteristics of both conflicted and non-conflicted patients in our study population, we more closely analyzed the relationship between cumulative time on dialysis prior to an evaluation for transplant and decisional conflict. The crude results of this study suggest that time on dialysis $\geq$1 year may have an effect on patients' ability to make decisions about treatment options for their kidney disease. Patients on dialysis for at least one year prior to their evaluation were more likely to feel conflicted or uncertain about their treatment options compared to patients who had not yet initiated dialysis. On the other hand, contradictory to our hypothesis, patients on dialysis less than one year prior to evaluation were not more or less likely to feel conflicted about their treatment options compared to patients who had never been on dialysis. After adjusting for demographic and clinical characteristics our results were similar. However, after further adjustments for socioeconomic characteristics, the effect of dialysis ≥1 year on decisional conflict moderately weakened, while the effect of dialysis <1 year on decisional conflict remained null.

We hypothesized that a longer time spent on dialysis by an ESRD patient prior to evaluation by a transplant nephrologist increases ESRD patients' likelihood for decisional conflict. Despite our results not aligning with our hypothesized dose-response relationship, our findings are theoretically plausible. Patients who have not yet initiated dialysis may feel more conflicted about their treatment options given they have not experienced life on dialysis, while patients who are evaluated shortly after initiating dialysis (less than one year) may feel more certain about remaining on the current course of treatment or improving their quality of life and chance of survival by pursuing transplantation. Additionally, patients on dialysis for greater than one year prior to evaluation may feel more conflicted because they have not been previously educated about their treatment options, do not feel supported in their decision to pursue transplantation, or lack interest in deviating from their current treatment method, among other reasons. In an ideal world, ESRD patients would feel confident, certain, and supported about their decision to undergo kidney transplantation at the time of their evaluation with a transplant nephrologist. Therefore, intervention efforts to increase access to transplant need to be implemented when patients are first diagnosed with ESRD, if not before.

To our knowledge, no previous studies have evaluated patient uncertainty when making treatment decisions about kidney disease using the decisional conflict scale within the United States ESRD population. However, O'Connor's decisional conflict scale has been utilized in previous cancer literature to assess the effectiveness of a decision aid utilized by patients deciding between treatment options. In a randomized control trial in Hong Kong, researchers used the decisional conflict scale to evaluate Chinese women deciding whether or not to pursue immediate breast reconstruction surgery before and after using a decision aid (45). The results suggested that women who used the decision aid had statistically significantly less decisional conflict (P=0.016) than women in the control group (45). Second, a cross-sectional study used the low literacy version of the decisional conflict scale, identical to the one used in our study, to evaluate the level of decisional conflict before and after using a mammography screening decision aid among women at rural primary clinics, age 40-49 (46). The results suggested that women felt less conflicted about mammography screening after using the decision aid (46.33 versus 8.33; Z=-7.225; p<0.001) (46). Finally, a cross-sectional study of 60 former or current smokers, who were non-lung cancer patients, was conducted to evaluate the effectiveness of a lung cancer screening decision aid. The participants' decisional conflict score decreased, i.e. on average, the patients' scores were closer to 0, after using the decision aid (p=<0.001) (47). Results from the aforementioned studies indicate that patients often enter evaluation appointments with medical providers feeling conflicted about how to best treat their chronic illness and subsequently benefit from the use of educational tools, more specifically a decision aid. To our knowledge, no previous studies have investigated our particular research question and therefore, we are unable to directly compare our results to findings in previous literature.

Study Strengths and Limitations

The geographic diversity of our study population is a major strength of our study. Study participants were recruited from three large transplant centers in different regions of the country, which increases the representativeness of our study population. It may be possible to extend the results of our analyses to ESRD patients evaluated at transplant centers not included in our study. Second, the study design made it simple and convenient to complete data collection in a short time period. By using a cross-sectional design, we did not have to wait through long period of follow-up before initiating preliminary analyses and being able to collect all variables at one time point.

This study does have its limitations, however. First, although we recruited ESRD patients and collected data from transplant centers located in different regions of the country, there are issues of external validity. More specifically, researchers recruiting ESRD patients from dialysis facilities or primary care clinics, for example, may not be able to compare their findings to the results of our analyses due to differences between the type of care ESRD patients receive at each of these institution types. It is possible for the demographic, clinical, and socioeconomic make-up of ESRD patients far along in the transplant evaluation process (i.e., being evaluated by a transplant nephrologist) to deviate from ESRD patients who have not yet begun this course of action. Given these reasons, we must be cautious not to generalize our findings to all ESRD patients and should take this into consideration when moving forward with alternative research questions based upon our findings.

Second, despite our best efforts to collect demographic and clinical data via the EMR to verify data collected in the baseline survey, some patient data was not able to be abstracted. Given that the survey data was self-reported, there is potential for recall bias. For example, patients were asked what type of dialysis they were presently on, if any, and patients may not know or remember whether they are on hemodialysis or peritoneal dialysis. If dialysis type was missing from a patient's EMR, we were not able to verify the accuracy of their response in the survey. Finally, the survey was most-often administered to patients via iPad, which could potentially lead to measurement bias. Some patients may not be as comfortable or familiar using an iPad as others, which in turn could have led to inaccurate responses or the accidental skipping of questions.

Conclusions

In conclusion, our research suggests that decisional conflict may be prevalent among the ESRD population. More specifically, our analyses found that a longer time spent on dialysis prior to being evaluated for a kidney transplant could increase the likelihood of decisional conflict among ESRD patients. While previous studies have evaluated the validity of O'Connor's DCS as an accurate assessment of patients' uncertainty when making decisions about their medical treatment, this scale has never been used, to our knowledge, among ESRD patients deciding between dialysis and transplantation. Our study results can be utilized by other researchers for further investigation of how decisional conflict regarding treatment options can impact health outcomes in ESRD patients nationwide. Our findings support the validity of the decisional conflict scale and introduce a potential inverse association between time on dialysis ≥1 year prior to evaluation and decisional conflict within the ESRD population. The latter also provides additional evidence for research previously identifying an association between shorter cumulative time spent on dialysis and increased survival advantage in ESRD patients (48).

Further identification of characteristics of patients on dialysis ≥1 year prior to evaluation with a transplant nephrologist could help inform future intervention efforts to improve patients' abilities to make decisions about the treatment of their kidney disease. Additionally, further evaluating patients with higher decisional conflict could lead to identification of characteristics that most often contribute to feelings of uncertainty in ESRD patients, i.e., lack of social support or absence of discussion with medical providers about kidney transplantation. Using the decisional conflict scale as a measurement tool, continued research among the ESRD population is needed to determine why a substantial proportion of ESRD patients still feel uncertain about undergoing a transplant at their first evaluation appointment with a transplant nephrologist.

References

1. National Chronic Kidney Disease Fact Sheet, 2014. *Centers for Disease Control and Prevention*.
2. USRDS 2015 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. *National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases,*.
3. American Kidney Fund. Rockville, MD; 2015. (Accessed December 17, 2015).
4. National Kidney Foundation. New York, NY; October, 2015. (Accessed December 17, 2015).
5. Jha V, Garcia-Garcia G, Iseki K, et al. Chronic kidney disease: global dimension and perspectives. *Lancet (London, England)* 2013;382(9888):260-72.
6. Patzer RE, McClellan WM. Influence of race, ethnicity and socioeconomic status on kidney disease. *Nature reviews Nephrology* 2012;8(9):533-41.
7. Freedman BI, Volkova NV, Satko SG, et al. Population-based screening for family history of end-stage renal disease among incident dialysis patients. *American journal of nephrology* 2005;25(6):529-35.
8. McClellan WM, Warnock DG, Judd S, et al. Association of family history of ESRD, prevalent albuminuria, and reduced GFR with incident ESRD. *American journal of kidney diseases : the official journal of the National Kidney Foundation* 2012;59(1):25-31.
9. Choi AI, Weekley CC, Chen SC, et al. Association of educational attainment with chronic disease and mortality: the Kidney Early Evaluation Program (KEEP).

American journal of kidney diseases : the official journal of the National Kidney Foundation 2011;58(2):228-34.

10. Greer RC, Cooper LA, Crews DC, et al. Quality of patient-physician discussions about CKD in primary care: a cross-sectional study. *American journal of kidney diseases : the official journal of the National Kidney Foundation* 2011;57(4):583-91.

11. Danovitch GM. *Options for Patients with Kidney Failure. In: Danovitch GM, ed. Handbook of Kidney Transplantation*. 2nd ed. Philadelphia: Lippincott Williams & Wilkins; 2005.

12. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2011;11(10):2093-109.

13. Saunders MR, Cagney KA, Ross LF, et al. Neighborhood poverty, racial composition and renal transplant waitlist. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2010;10(8):1912-7.

14. Mathur AK, Ashby VB, Sands RL, et al. Geographic variation in end-stage renal disease incidence and access to deceased donor kidney transplantation. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2010;10(4 Pt 2):1069-80.

15. Braveman P. Health disparities and health equity: concepts and measurement. *Annual review of public health* 2006;27:167-94.

16. Alexander GC, Sehgal AR. Barriers to cadaveric renal transplantation among blacks, women, and the poor. *Jama* 1998;280(13):1148-52.

17. Patzer RE, Pastan SO. Kidney transplant access in the Southeast: view from the bottom. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2014;14(7):1499-505.

18. Patzer RE, Perryman JP, Schrager JD, et al. The role of race and poverty on steps to kidney transplantation in the Southeastern United States. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2012;12(2):358-68.

19. Berkman ND, Davis TC, McCormack L. Health literacy: what is it? *Journal of health communication* 2010;15 Suppl 2:9-19.

20. Dageforde LA, Cavanaugh KL. Health literacy: emerging evidence and applications in kidney disease care. *Adv Chronic Kidney Dis* 2013;20(4):311-9.

21. Kazley AS, Hund JJ, Simpson KN, et al. Health literacy and kidney transplant outcomes. *Prog Transplant* 2015;25(1):85-90.

22. Kucirka LM, Grams ME, Balhara KS, et al. Disparities in provision of transplant information affect access to kidney transplantation. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2012;12(2):351-7.

23. Ashby VB, Kalbfleisch JD, Wolfe RA, et al. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons* 2007;7(5 Pt 2):1412-23.

24. Patzer RE, Basu M, Larsen CP, et al. iChoose Kidney: A Clinical Decision Aid for Kidney Transplantation Versus Dialysis Treatment. *Transplantation* 2016;100(3):630-9.

25. Patzer RE, Basu M, Larsen CP, et al. iChoose Kidney: A Clinical Decision Aid for Kidney Transplantation Versus Dialysis Treatment. *Transplantation* 2015.

26. Prevention. CfDCa. Chronic Kidney Disease Surveillance System-United States,. (http://www.cdc.gov/ckd). (Accessed).

27. LeBlanc A, Kenny DA, O'Connor AM, et al. Decisional conflict in patients and their physicians: a dyadic approach to shared decision making. *Medical decision making : an international journal of the Society for Medical Decision Making* 2009;29(1):61-8.

28. O'Connor A. User Manuel-Decisional Conflict Scale. 1993. (http://www.jefferson.edu/content/dam/tju/jmc/files/medical_oncology/popsci/decisionalconflictscale.pdf). (Accessed 8/10/2015).

29. Koedoot N, Molenaar S, Oosterveld P, et al. The decisional conflict scale: further validation in two samples of Dutch oncology patients. *Patient education and counseling* 2001;45(3):187-93.

30. Song MK, Sereika SM. An evaluation of the Decisional Conflict Scale for measuring the quality of end-of-life decision making. *Patient education and counseling* 2006;61(3):397-404.

31. Guerriere D, Llewellyn-Thomas H. Substitute decision-making: measuring individually mediated sources of uncertainty. *Patient education and counseling* 2001;42(2):133-43.

32. Meier-Kriesche HU, Port FK, Ojo AO, et al. Effect of waiting time on renal transplant outcome. *Kidney international* 2000;58(3):1311-7.

33. Meier-Kriesche HU, Kaplan B. Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: a paired donor kidney analysis. *Transplantation* 2002;74(10):1377-81.

34. Murray MA, Brunier G, Chung JO, et al. A systematic review of factors influencing decision-making in adults living with chronic kidney disease. *Patient education and counseling* 2009;76(2):149-58.

35. Saad MM, El Douaihy Y, Boumitri C, et al. Predictors of quality of life in patients with end-stage renal disease on hemodialysis. *International journal of nephrology and renovascular disease* 2015;8:119-23.

36. Gurkan A, Pakyuz SC, Demir T. Stress Coping Strategies in Hemodialysis and Kidney Transplant Patients. *Transplant Proc* 2015;47(5):1392-7.

37. Traino HM, Nonterah CW, Cyrus JW, et al. Disparities in the completion of steps to kidney transplantation: protocol for a systematic review. *BMJ open* 2015;5(9):e008677.

38. Churak JM. Racial and ethnic disparities in renal transplantation. *Journal of the National Medical Association* 2005;97(2):153-60.

39. Finkelstein FO, Story K, Firanek C, et al. Perceived knowledge among patients cared for by nephrologists about chronic kidney disease and end-stage renal disease therapies. *Kidney international* 2008;74(9):1178-84.

40. Mehrotra R, Marsh D, Vonesh E, et al. Patient education and access of ESRD patients to renal replacement therapies beyond in-center hemodialysis. *Kidney international* 2005;68(1):378-90.

41. Patzer RE, Basu M, Mohan S, et al. A Randomized Controlled Trial of a Mobile Clinical Decision Aid to Improve Access to Kidney Transplantation: iChoose Kidney. *Kidney international* 2016;Under Review.

42. Lipkus IM, Samsa G, Rimer BK. General performance on a numeracy scale among highly educated samples. *Medical decision making : an international journal of the Society for Medical Decision Making* 2001;21(1):37-44.

43. Weiss BD, Mays MZ, Martz W, et al. Quick assessment of literacy in primary care: the newest vital sign. *Annals of family medicine* 2005;3(6):514-22.

44. Kleinbaum DG. *Logistic Regression: A Self-Learning Text.* Third Edition ed. ed. New York: Springer; 2010.

45. Lam WW, Chan M, Or A, et al. Reducing treatment decision conflict difficulties in breast cancer surgery: a randomized controlled trial. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2013;31(23):2879-85.

46. Eden KB, Scariati P, Klein K, et al. Mammography Decision Aid Reduces Decisional Conflict for Women in Their Forties Considering Screening. *Journal of women's health (2002)* 2015.

47. Lau YK, Caverly TJ, Cao P, et al. Evaluation of a Personalized, Web-Based Decision Aid for Lung Cancer Screening. *American journal of preventive medicine* 2015.

48. Mange KC, Joffe MM, Feldman HI. Dialysis prior to living donor kidney transplantation and rates of acute rejection. *Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association* 2003;18(1):172-7.

Tables and Figures

Table 1. Selected characteristics of end stage renal disease patients (n=464) by time on dialysis prior to kidney transplant evaluation at three U.S. transplant centers in 2014-2015.

Characteristics[a]	Study Population (n = 464)	Preemptive Referral[b] (n = 152)	Dialysis <1 year (n = 156)	Dialysis ≥1 year (n = 156)	P-Value[c]
Demographic Characteristics					
Age, mean ± SD, years	50.6 ± 10.2	50.5 ± 10.1	49.8 ± 10.2	51.5 ± 10.2	0.32
Male, %	62.1	57.2	62.8	66.0	0.28
Race/Ethnicity, %					<0.01
African American	47.6	25.7	50.0	66.7	
White, non-Hispanic	34.9	51.3	32.7	21.2	
White, Hispanic	10.6	13.8	10.9	7.1	
Other[d]	6.7	9.2	6.4	4.5	
Institution, %					
Transplant Center A	34.1	17.8	38.5	45.5	
Transplant Center B	30.8	41.5	28.2	23.1	
Transplant Center C	35.1	40.8	33.3	31.4	
Clinical Characteristics[e]					
Comorbidities, %					
BMI >35 kg/m^2	18.3	17.1	18.0	19.9	0.81
Hypertension	78.7	79.0	73.1	84.0	0.06
Diabetes	37.9	27.6	42.3	43.6	0.01
Cardiovascular Disease	9.3	6.6	9.0	12.2	0.24
Albumin < 3.5 g/dL	18.1	14.6	20.8	18.8	0.37
Type of Dialysis, %					<0.01
Not on Dialysis	32.8	-	-	-	
Hemodialysis	51.5	-	71.8	81.4	
Peritoneal Dialysis	15.7	-	28.2	18.6	
Socioeconomic Characteristics[f]					
Married, %	58.8	64.5	56.4	55.8	0.16
Social Support[g], %	53.9	56.6	54.5	50.6	0.11
Education Level, %					<0.01
8th Grade or Less	2.4	0.7	0.6	5.8	
Some High School	5.6	2.0	4.5	10.3	
High School Diploma or GED	24.0	15.8	32.1	23.7	
Some College or Vocational School Degree	28.0	26.3	23.7	34.0	
College or Vocational School Degree	23.5	32.9	22.4	15.4	
Professional or Graduate Degree	15.3	21.1	15.4	9.6	
Employment Status, %					<0.01
Employed	38.8	58.6	37.8	20.5	
Unemployed	36.9	21.7	43.0	45.5	
Retired	22.4	17.8	18.0	31.4	
Primary Health Insurance Status, %					
Medicare	50.0	28.3	45.5	75.6	<0.01
Medicaid	30.4	17.8	28.9	44.2	<0.01
Private	52.2	73.0	51.9	32.1	<0.01
Household Income Before Taxes, %					<0.01
Less than $20,000	24.8	14.5	23.7	35.9	

$20,001 to $40,000	17.5	13.2	18.0	21.2	
$40,001 to $60,000	10.3	9.2	10.9	10.9	
$60,001 to $80,000	13.2	13.2	14.7	11.5	
Greater than $80,000	23.5	38.8	25.6	6.4	
Prefer Not to Answer	9.1	9.9	5.8	11.5	
Health Literacy Score[h], mean ± SD	3.6 ± 2.1	4.2 ± 1.9	3.7 ± 1.9	2.8 ± 2.1	<0.01
Numeracy Score[i], mean ± SD	6.1 ± 3.2	7.1 ± 3.3	6.1 ± 2.9	5.2 ± 3.2	<0.01
Decisional Conflict Score, mean ± SD	0 (0, 15)	8.9 ± 14.7	9.8 ± 16.0	12.2 ± 17.3	0.16

[a] Not all percentages will add up to 100% due to missing data. Characteristics with missing data: race (n=1), albumin <3.5 g/dL (n=17), marital status (n=5), educational status (n=6), and literacy/numeracy (n=22)

[b] Patient evaluated for transplantation by a transplant nephrologist prior to initiating dialysis treatment

[c] By one-way ANOVA for continuous variables and chi^2 test for categorical variables

[d] Asian, Multiracial, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, Middle Eastern, East Indian

[e] Clinical characteristics collected the day of patient's transplantation evaluation appointment

[f] Socioeconomic characteristics self-reported the day of patient's transplant evaluation appointment

[g] Defined as at least one family member or friend accompanying the patient to the kidney transplant evaluation

[h] Literacy score calculated using Newest Vital Sign, NVS, on a scale from 0 – 6

[i] Numeracy score calculated using the Lipkus scale, on a scale from 0 – 11

Table 2. Selected characteristics of end stage renal disease patients by decisional conflict score at three large transplant centers (n=464), 2014-2015.

Characteristics[a]	**Study Population (n = 464)**	**No Decisional Conflict: Score = 0 (n = 239)**	**Any Decisional Conflict: Score > 0 (n = 225)**	**P-Value**[b]
Demographic Characteristics				
Age, mean ± SD, years	50.6 ± 10.2	50.2 ± 10.5	51.1 ± 9.8	0.36
Male, %	62.1	56.1	68.4	0.01
Race/Ethnicity, %				<0.01
African American	47.6	41.8	53.8	
White, non-Hispanic	34.9	42.3	27.1	
White, Hispanic	10.6	8.4	12.9	
Other[c]	6.7	7.1	6.2	
Institution, %				
Transplant Center A	34.1	30.6	37.8	
Transplant Center B	30.8	31.8	29.8	
Transplant Center C	35.1	37.7	32.4	
Clinical Characteristics[d]				
Comorbidities, %				
BMI >35 kg/m^2	18.3	16.7	20.0	0.45
Hypertension	78.7	78.2	79.1	0.82
Diabetes	37.9	34.7	41.3	0.14
Cardiovascular Disease	9.3	8.4	10.2	0.49
Albumin < 3.5 g/dL	18.1	15.5	21.0	0.13
Type of Dialysis, %				0.52
Not on Dialysis	32.8	34.7	30.7	
Hemodialysis	51.5	51.1	52.0	
Peritoneal Dialysis	15.7	14.2	17.3	
Time on dialysis, median (Q1, Q3), days	361 (170, 1175)	293 (168, 1027)	441 (179, 1240)	0.30
Socioeconomic Characteristics[e]				
Married, %	58.8	64.0	53.3	0.02
Social Support[f], %	53.9	55.2	52.4	0.27
Education Level, %				<0.01
8th Grade or Less	2.4	1.7	3.1	
Some High School	5.6	3.8	7.6	
High School Diploma or GED	24.0	17.2	31.1	
Some College or Vocational School Degree	28.0	29.7	26.2	
College or Vocational School Degree	23.5	25.1	21.8	
Professional or Graduate Degree	15.3	20.5	9.8	
Employment Status, %				0.04
Employed	38.8	44.4	32.9	
Unemployed	36.9	33.5	40.4	
Retired	22.4	20.1	24.9	
Primary Health Insurance Status, %				
Medicare	50.0	51.1	48.9	0.64
Medicaid	30.4	26.8	34.2	0.08
Private	52.2	59.0	44.9	<0.01

Household Income Before Taxes, %				0.03
Less than $20,000	24.8	20.5	29.3	
$20,001 to $40,000	17.5	15.5	19.6	
$40,001 - $60,000	10.3	10.0	10.7	
$60,001 - $80,000	13.2	15.9	10.2	
Greater than $80,000	23.5	28.0	18.7	
Prefer Not to Answer	9.1	8.4	9.8	
Health Literacy Score[g], mean ± SD	3.6 ± 2.1	4.0 ± 1.9	3.2 ± 2.1	<0.01
Numeracy Score[h], mean ± SD	6.1 ± 3.2	6.6 ± 3.2	5.6 ± 3.2	<0.01

---

[a] Not all percentages will add up to 100% due to missing data. Characteristics with missing data: race (n=1), albumin <3.5 g/dL (n=17), marital status (n=5), educational status (n=6), and literacy/numeracy (n=22)

[b] By t-test for continuous variables and chi^2 test for categorical variables

[c] Asian, Multiracial, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, Middle Eastern, East Indian

[d] Clinical characteristics collected the day of patient's transplantation evaluation appointment

[e] Socioeconomic characteristics self-reported the day of patient's transplant evaluation appointment

[f] Defined as at least one family member or friend accompanying the patient to the kidney transplant evaluation

[g] Literacy score calculated using Newest Vital Sign, NVS, on a scale from 0 – 6

[h] Numeracy score calculated using the Lipkus scale, on a scale from 0 – 11

Table 3. Crude and adjusted associations of decisional conflict (DCS >0) with time on dialysis prior to kidney transplant evaluation among end stage renal disease patients at three U.S. transplant centers in 2014-2015.

	Odds Ratios (95% CI)	
Presence of Decisional Conflict	Dialysis <1 Year vs. Preemptive Referral	Dialysis ≥ 1 Year vs. Preemptive Referral
Model 1: Crude[a]	0.95 (0.61, 1.50)	1.52 (0.97, 2.38)
Model 2: Clinical+demographic factors[b]	0.96 (0.51, 1.79)	1.40 (0.71, 2.75)
Model 3: Clinical+demographic+SES factors+geographic location[c]	0.96 (0.48, 1.93)	1.28 (0.60, 2.70)

Abbreviations: ESRD, End Stage Renal Disease; DCS, Decisional Conflict Score; SES, Socioeconomic Status

[a] Model 1: ORs from unconditional logistic regression models; n=464

[b] Adjusted for age, sex, race, serum albumin, and dialysis type; n=446 due to missing data

[c] Adjusted for age, sex, race, serum albumin, dialysis type, marital status, educational status, insurance status, health literacy, and institution; n=390 due to missing data

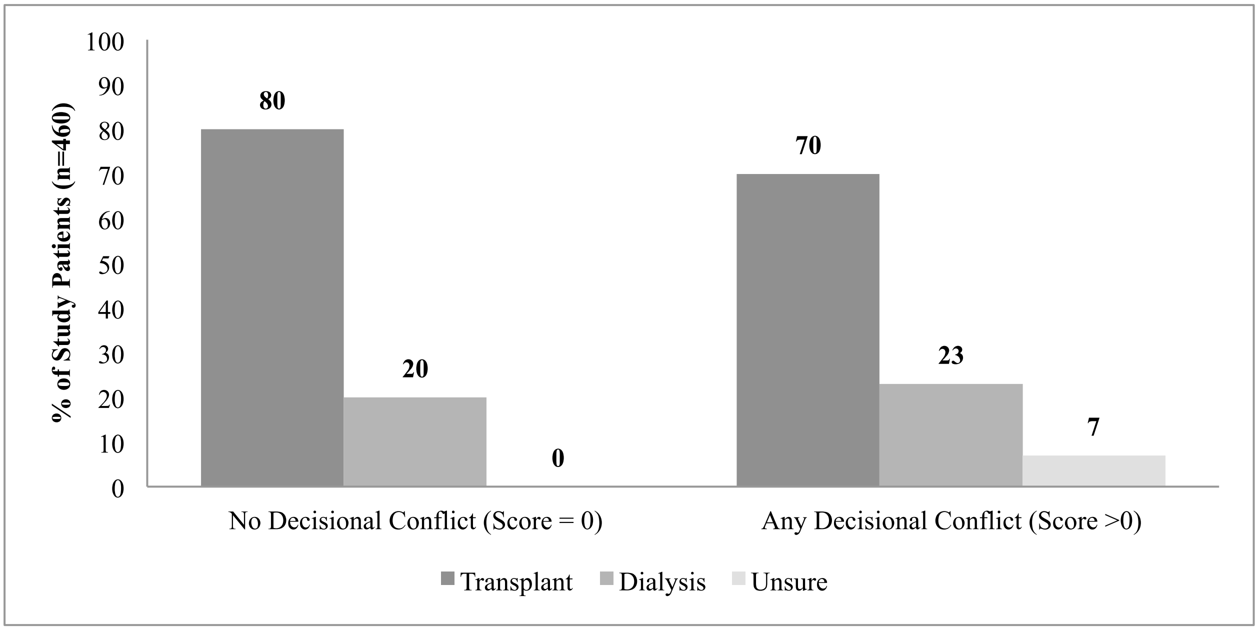

Figure 1. End stage renal disease treatment preferences (transplant, dialysis, unsure) among non-conflicted vs. conflicted end stage renal disease patients (n=460) at three U.S. transplant centers in 2014-2015.